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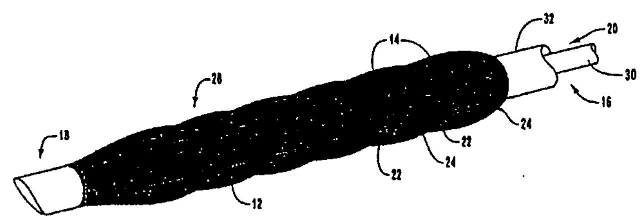
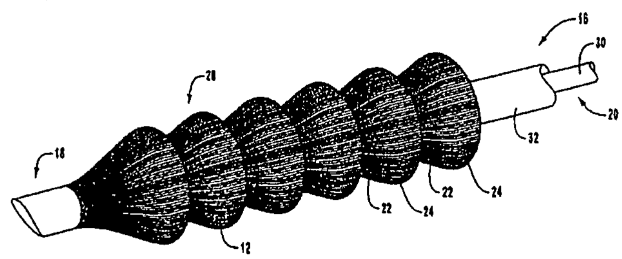
(54) **Title:** INTRAVASCULAR BLOOD-GAS EXCHANGER





(57) **Abstract:** An intravascular blood-gas exchanger (10) includes a plurality of gas permeable tubes or fibers (12) that are connected to a central gas conduit (16). The gas permeable tubes allow oxygen to be transferred into a patient's blood and carbon dioxide removed. The gas permeable tubes are preferably formed into one or more generally conical-shaped segments that can be selectively moved between a retracted position (fig.1), which allows the intravascular blood-gas exchanger to be inserted or removed from the patient, and an expanded position (fig.2) after the device is inserted into the patient and positioned such that the tubes are generally arranged in a predetermined pattern. The gas permeable tubes are preferably arranged to improve the flows of blood around the tubes and increase the gas transfer rate. The device in its retracted (furled) condition is small enough in cross-sectional diameter to be inserted, percutaneously and without the need for major invasive vascular surgery, in a blood vessel.

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INTRAVASCULAR BLOOD-GAS EXCHANGER

Cross-Reference to Related Applications

[01] The present application claims priority to and the benefit of United States Provisional Patent Application Serial No. 60/278,059, entitled IVOX-II, which was filed on March 22, 2001, and is hereby incorporated by reference in its entirety. The present application also claims prior to and the benefit of United States Patent Application Serial No. 09/935,411, which was filed on August 23, 2001, and is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

1. The Field of the Invention

[02] The present invention relates generally towards a lung assist device that transports oxygen into and carbon dioxide out of the circulating venous blood. More particularly, the present invention is directed towards an intravascular blood-gas exchanger that has increased efficiency, effectiveness, and safety in transporting oxygen and carbon dioxide for patients with advanced respiratory failure.

2. Description of Related Art

[03] Thousands of people suffer from inadequate blood gas exchange, which includes both inadequate blood oxygenation and inadequate removal of carbon dioxide from the blood. Inadequate blood gas exchange can be caused by many conditions or illnesses such as pneumonia, pneumonitis, atelectasis, various heart and circulatory ailments, fluid in the lungs, obstruction of

pulmonary ventilation, acute respiratory distress syndrome, or lung injury caused by heat, noxious gases and other factors.

[04] There are several types of conventional lung assist devices that attempt to supply oxygen and remove carbon dioxide from patients for short term. These devices can be conveniently separated into three categories: respirators, extracorporeal oxygenators and intravascular lung assist devices. In general, respirators are useful in improving the efficiency of a patient's blood gas exchange when used judiciously in low or moderate intensity. However, respirators are not suitable for use where a patient's damaged or diseased lungs require rest or are simply incapable of performing the required respiration. They are also not suitable for high-intensity blood-gas exchanges (high pressure, gas flow rate, and/or concentration of oxygen). Extracorporeal oxygenators, commonly referred to as heart-lung machines, usually take the form of extracorporeal membrane oxygenators (ECMOs) and are most frequently used for relatively short intervals, such as during surgery where the circulation through a patient's heart and lungs is temporarily bypassed. Extracorporeal oxygenators are generally not used for extended or long-term critical care because the machines are expensive to operate and require almost constant supervision and monitoring by skilled technicians. Conventional heart-lung machines also require the use of anticoagulants, which may create additional problems such as internal bleeding, especially when systematically administered on a long-term basis.

[05] These conventional respirators, however, place more strain on the lungs, which may be diseased or injured and unable to function at full capacity. In order to allow diseased or damaged lungs to heal, it is desirable to

allow the lungs to rest and then gradually increase their activity. Because conventional respirators place more strain and require more work from the lungs, this often prevents the lungs from healing or recovering. Additionally, these machines are often used in late stages of respiratory failure when patients have multi-organ failure from the inadequate blood-gas exchange and any additional stress to a patient could be critical.

[06] Extracorporeal oxygenators typically include a gas permeable membrane in which oxygen-rich gas flows on one side of the membrane and blood flows on the other side. As the blood flows along one side of the membrane, oxygen supplied to the other side of the membrane permeates through the membrane into the blood while carbon dioxide permeates through the membrane from the blood into the gas on the other side of the membrane. Oxygen will diffuse or travel across the membrane and enter the blood if there is a sufficient pressure gradient between the oxygen supply and the blood. In addition, carbon dioxide will diffuse from the blood, across the membrane, and into the gas supply. The membrane separating the blood from the gas allows oxygenation of the blood without introducing oxygen bubbles into the blood. The gas permeable membrane is typically either a microporous membrane that allows gas to transfer through the micropores or a continuous membrane that allows gas to exchange through the membrane without the gas and blood directly interfacing.

[07] Conventional intravascular lung assist devices (ILADs) include a device inserted into a patient's vena cava to provide oxygen and carbon dioxide exchange in the blood. Conventional ILADs include a bundle of tiny gas-permeable tubes that extend between a pair of headers connected to a gas

supply and gas exhaust system. In particular, oxygen-rich gas is supplied to one end of the tubes and carbon-dioxide-rich gas is removed from the other end of the tubes. When located in the vena cava, the device operates as an intravascular artificial lung to assist in the function of a patient's diseased or damaged lungs.

[08] Known ILAD devices are typically positioned within the patient's venae cavae by a two-step process. First, an incision is made in the patient's femoral or iliac vein or internal jugular vein. A large cannula is inserted into this surgically incised access vein through which a radiopaque guide catheter is inserted into the access vein and is guided through the superior and inferior venae cavae and right atrium using a fluoroscope for control. Second, the ILAD device is advanced over the guide catheter and properly positioned in the venae cavae. The cannula and guide wire are then removed and the incised access vein is repaired surgically.

[09] While this method of inserting the ILAD device into a patient's venae cavae has been successfully demonstrated, still there are several drawbacks. For example, the ILAD device must have a small outside diameter to be able to pass through the relatively narrow access veins such as the jugular or femoral vein. As a result, when the device is within the venae cavae, which has a much larger diameter than the jugular vein, the blood flow may bypass the gas permeable tubes. Accordingly, the contact of the blood with the surface of the gas permeable tubes is reduced.

[010] In addition, conventional ILAD devices may also include a relatively bulky bundle of gas-permeable tubes. These gas-permeable tubes are relatively long, generally 40-50 cm, and often free floating within the venae

cavae. Because of the size and configuration of the relatively bulky bundle of long, gas-permeable tubes, conventional ILAD devices are often very difficult to insert and/or remove from the patient. In particular, even when the gas-permeable tubes are furled or folded, the device has a relatively large outside diameter that requires large insertion and removal passageways. Moreover, the long tubes have limited gas-flow rates because of their small inside diameter, which creates a large resistance to gas flow.

[011] Further, conventional ILAD devices often have low gas transfer rates because of relatively poor interaction between the blood and the gas-permeable tubes. For example, conventional ILAD devices often have problems of stagnation areas forming around one or more of the tubes, which prevents the blood from properly flowing through the venae cavae and prevents blood gas exchange. Conventional ILAD devices also often have considerable, undesirable laminar flow of the blood, which forms boundary layers between the gas-permeable tubes and the blood. Laminar flow of the blood over the gas-permeable tubes is undesirable because the boundary layer prevents blood gas exchange with the majority of the blood, which does not contact the tubes. Further, conventional ILAD devices often have a random or suboptimal arrangement of the gas-permeable tubes such that only a portion of the tubes is in contact with the blood flow. Thus, the useful surface area of the gas-permeable tubes is limited because the blood flow does not interact with all of the gas-permeable tubes. This requires conventional ILAD devices to have an increased number of tubes to make up for this loss of useful surface area, further increasing its bulkiness.

[012] It is also important to note that all conventional ILAD devices are sufficiently thrombogenic when present in the patient's venous blood stream that systemic anticoagulation is necessary to prevent or reduce the incidence of blood-clot formation or fibrin deposits on the tubes or within the venous blood, which may decrease gas transfer efficiency or embolize to the lungs, causing death of the patient. Less than optimum control of the necessary systemic anticoagulation may result in serious internal bleeding (over-anticoagulation) or clot formation and/or pulmonary emboli (under-anticoagulation).

[013] Desired improvements in the design, materials, and methods of application of conventional ILAD devices require the device to: 1) be more efficient in gas-transfer (deliver more oxygen into and remove more carbon dioxide from circulating venous blood); 2) be smaller in cross-sectional diameter when furled (compacted for insertion) so that insertion and removal can be accomplished without vascular surgery; 3) be expandable within the venae cavae to create improved blood-flow patterns (mixing of blood) as it flows around the tubes; 4) be sufficiently non-thrombogenic and biocompatible within the venae cavae such that systemic anticoagulation during use of the ILAD is not necessary; and 5) be operated in a manner that prevents leakage of gas directly into the blood.

BRIEF SUMMARY OF THE INVENTION

[014] A need therefore exists for an intravascular blood-gas exchanger that provides improved gas transfer and minimizes or overcomes the above-described problems and disadvantages. The present invention addresses,

reduces, or overcomes all five of the aforementioned disadvantages of current ILAD devices.

[015] One aspect of the present invention is an intravascular blood-gas exchanger in which oxygen (O_2) is added to and carbon dioxide (CO_2) is removed from the circulating blood without further damaging, irritating or injuring the lungs. The intravascular blood-gas exchanger includes a plurality of hollow fibers or gas-permeable tubes that are used to transfer and carry oxygen and carbon dioxide in and out of the body. The hollow fibers are preferably arranged into one or more generally conical-shaped segments that are retractable to allow insertion of the device into the patient and expandable to fill all or a portion of the venae cavae during blood-gas exchange. Advantageously, the design and arrangement of the hollow fibers allow the transportation of more oxygen and carbon dioxide, which increases the blood gas transfer rate, thus increasing its efficiency.

[016] Another aspect of the intravascular blood-gas exchanger allows easier insertion and removal of the device from the patient. In particular, the device has a very small insertion and removal outside diameter. The small insertion and removal outside diameter makes the device much easier to insert and remove because, for example, no open surgical venotomy is required. Instead, the insertion and removal of the intravascular blood-gas exchanger is made through a single opening such as a venapuncture. Additionally, the device can be inserted and removed through a relatively small access vessel, such as the iliac, femoral or jugular vein.

[017] A further aspect of the intravascular blood-gas exchanger is that the outside diameter of the generally conical-shaped hollow fiber segments is

readily adjustable to provide either the small, compact insertion diameter or the larger, expanded diameter after the device is positioned within the patient for blood gas exchange. In particular, the generally conical-shaped hollow fiber segments can be readily adjusted from a retracted position for insertion into the patient to an expanded position for blood gas exchange. A generally ring-shaped support structure and one or more struts may be used to control and guide the movement of the hollow fiber segments between the expanded and retracted positions. Advantageously, this allows the device to open and close like an umbrella, which permits the hollow fiber segments to be quickly and easily moved between the expanded and retracted positions.

[018] Yet another aspect of the intravascular blood-gas exchanger is that fewer adverse side effects occur in comparison to conventional ILADs. For example, the intravascular blood-gas exchanger can be used earlier in the treatment of patients because of the ease and simplicity of insertion and removal of the device. Additionally, no invasive surgery is necessary to insert and remove the device. Further, the intravascular blood-gas exchanger allows the lungs and respiratory system of the patient time to rest and heal and is not injurious to the lungs. Advantageously, because the intravascular blood-gas exchanger requires no systemic anticoagulation, that minimizes or eliminates potential problems such as internal bleeding and/or clot or embolus formation.

[019] Still another aspect of the intravascular blood-gas exchanger is that the hollow fibers are arranged into a specific pattern or array that improves the rate of gas transfer. For example, the hollow fibers may be arranged into a continuous hollow fiber array. Preferably, the hollow fibers are arranged into a plurality of generally conical-shaped hollow fiber segments. Significantly,

the intravascular blood-gas exchanger may include a single generally conical-shaped hollow fiber segment or a plurality of generally conical-shaped hollow fiber segments depending, for example, upon the intended use of the intravascular blood-gas exchanger or rate of gas transfer required.

[020] A further aspect of the intravascular blood-gas exchanger is that the arrangement of the hollow fibers into the generally conical-shaped segments helps prevent laminar blood flow around the fibers. This promotes better mixing of the blood and eliminates a boundary layer from being formed between the hollow fibers and the majority of the blood flow, which improves gas transfer efficiency. Advantageously, the generally conical-shaped segments also help maximize the surface area of the fibers in contact with the blood flow. This increases the interaction of the blood with the fibers, which also increases gas transfer efficiency.

[021] Yet another aspect of the intravascular blood-gas exchanger is that the hollow fibers are connected to a central gas conduit and, in the retracted position, the fibers are furled or folded about the central gas conduit, which decreases the cross-sectional diameter of the fiber bundle and thereby facilitates insertion of the device into the patient. In the expanded position, the hollow fibers extend radially outward from the central gas conduit to permit blood-gas exchange. Advantageously, depending upon the diameter or size of the artery or vessel in which the device is located, such as the venae cavae, the fibers can extend outwardly from the central gas conduit at a relatively small angle such as about ten to twenty degrees (10°-20°) or up to a relatively large angle of about seventy to ninety degrees (70°-90°), or more.

Significantly, the fibers can expand radially outward to fill all or just a portion of the vessel or artery.

[022] Another aspect of the intravascular blood-gas exchanger is the central gas conduit includes dual lumens or tubes to supply oxygen to the hollow fibers and exhaust carbon dioxide from the device. Preferably, the central gas conduit includes two coaxial lumens with one of the lumens attached to a source of oxygen-rich gas and the other lumen connected to an exhaust system. The oxygen-rich gas flows through the lumen and into the hollow fibers where the venous blood flows around the fibers. Oxygen diffuses or passes through the walls of the fibers and into the blood, which causes blood oxygenation. Simultaneously, carbon dioxide passes from the blood, through the walls of the fibers and into the other lumen where it is exhausted from the body. Preferably suction is applied to the exhaust lumen to augment the gas flow through the fibers. Advantageously, this decreases or eliminates the risk of bubbling, foaming, or an air embolism forming in the patient.

[023] A further aspect of the intravascular blood-gas exchanger is a support structure that helps control or guide the expansion of the generally conical-shaped hollow fiber segments from the retracted position to the expended position. Additionally, one or more struts or supports may be used to assist in the expansion of the segments into the expended position and/or maintain the segments in the open position. Preferably, the struts are attached to the support structure to help expand and maintain the segments in the open position. Advantageously, the generally conical-shaped hollow fiber segments, support structure and struts are very durable and have a decreased susceptibility to mechanical failure.

[024] Another aspect of the intravascular blood-gas exchanger is that the generally conical-shaped hollow fiber segments may be sized and configured to fit arteries and vessels of different sizes. For example, the conical-shaped segments may be expended to fit within the relatively small venae cavae of a youth or the conical-shaped segments may be expanded into a larger area to fit within the venae cavae of an adult. Thus, the intravascular blood-gas exchanger may have different sizes depending upon the radial outward expansion of the hollow fiber segments.

[025] Still another aspect of the intravascular blood-gas exchanger is that the hollow fibers have a thinner gas-transfer membrane, which increases the rate of transfer of gas with the blood. Preferably, the hollow fibers are microporous hollow fibers with a gas permeable coating comprising a 0.1 micron siloxane fluorinated polymer instead of the 1.0 micron siloxane as known in the art. Additionally, the fibers may include an improved thromboresistant and blood-compatible coating.

[026] Advantageously, these and other aspects significantly enhance the safety, performance, and gas transfer capabilities of the intravascular blood-gas exchanger. Additionally, the intravascular blood-gas exchanger described above benefits the patient because invasive surgery is not required for insertion or removal and greater gas transfer occurs. Further, the simplicity, ease of operation and enhanced capabilities allow the device to be used in a wider variety of situations and different types of patients.

[027] These and other aspects, features and advantages of the present invention will become more fully apparent from the following description of the preferred embodiments and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[028] The appended drawings contain figures of preferred embodiments to further clarify the above and other aspects, advantages and features of the present invention. It will be appreciated that these drawings depict only preferred embodiments of the invention and are not intended to limits its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[029] Figure 1 is a perspective view of the intravascular blood-gas exchanger in accordance with a preferred embodiment of the present invention, illustrating a series of conical-shaped woven hollow fiber sheets in a retracted or furled position;

[030] Figure 2 is a perspective view of the intravascular blood-gas exchanger shown in Figure 1, illustrating the conical-shaped woven hollow fiber sheets in an expanded position;

[031] Figure 3 is an enlarged, partial cross-sectional side view of the intravascular blood-gas exchanger in accordance with another preferred embodiment of the present invention;

[032] Figure 4 is a perspective view of the intravascular blood-gas exchanger in accordance with still another preferred embodiment of the present invention, illustration the conical-woven hollow fiber sheets in a compressed position;

[033] Figure 5 is a perspective view of the intravascular blood-gas exchanger shown in Figure 4, illustrating the hollow fiber sheets in an elongated position; and

[034] Figure 6 is an enlarged, partial cross-sectional side view of the intravascular blood-gas exchanger shown in Figure 4, illustrating the hollow fiber sheets in the compressed position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[035] The present invention is directed towards an improved intravascular blood-gas exchanger for use in connection with respiratory illnesses and failure. The principles of the present invention, however, are not limited to intravascular blood-gas exchangers. It will be understood that, in light of the present disclosure, the device disclosed herein can be successfully used in connection with other types of surgical and medical equipment.

[036] Additionally, to assist in the description of the intravascular blood-gas exchanger, words such as top, bottom, front, rear, right and left are used to describe the accompanying figures. It will be appreciated, however, that the present invention can be located in a variety of desired positions–including various angles, sideways and even upside down. A detailed description of preferred embodiments of the intravascular blood-gas exchanger now follows.

[037] As shown in Figure 1, an intravascular blood-gas exchanger 10 includes a plurality of hollow fibers or gas-permeable tubes 12 that are bundled together into a number of segments 14 about a central gas conduit 16. The intravascular blood-gas exchanger 10 includes a proximal end 18, which is typically inserted into the patient first, and a distal end 20. The hollow fibers 12 in each of the segments 14 also include a proximate end 22 and a distal end 24, respectively. As illustrated in Figure 1, the segments 14 are located in an axially compressed or retracted position 26 in which the fibers

are furled or folded about the central gas conduit 16 in a tightly compressed or bundled configuration.

[038] As shown in Figures 2 and 3, the segments 14 can also be positioned in an expanded position 28 in which at least a portion of the hollow fibers 12 extend radially outward from the central gas conduit 16. When the segments 14 are in the retracted position 26, that facilitates the insertion and removal of the intravascular blood-gas exchanger 10 from the patient. On the other hand, when the segments 14 are in the expanded position 28, the fibers 12 are positioned for blood oxygenation and gas transfer.

[039] Advantageously, the segments 14 in the retracted position 26 have a relatively small outside diameter, which allows the device to be quickly and easily inserted into the patient. In addition, the outside diameter of the segments 14 in the retracted position 26 is preferably sufficiently small to allow the device to be inserted into the patient through a peripheral vein. Significantly, the segments 14 can be expanded into the expanded position 28 such that the hollow fibers 12 fill all or a portion of the desired vein or artery, such as the venae cavae, which allows efficient blood oxygenation to occur.

[040] As seen in Figures 1 and 2, six segments 14 are preferably disposed about the central gas conduit 16 and, as seen in Figure 3, the hollow fibers 12 forming the segments are preferably continuous such that gas flows directly from one segment to the next segment. One skilled in the art will appreciate, however, that the segments 14 do not have to be directed connected together and any number of segments could be connected together. Additionally, the hollow fibers 12 do not have to be continuous and, for example, various segments could be connected to the central gas conduit 16. One skilled in the

art will also appreciate that the intravascular blood-gas exchanger 10 can include any suitable number of segments 14 depending, for example, upon the desired amount of gas to be transferred or size of the patient.

[041] As shown in the attached figures, the hollow fibers 12 are generally positioned adjacent to or proximate neighboring hollow fibers. It will be understood that the hollows fibers 12 may form a generally contiguous structure and/or a distance may separate the fibers. Preferably, the hollow fibers 12 are separated by a distance such that the fibers do not significantly increase the resistance to blood flow within the patient. More preferably, the hollow fibers 12 are positioned such that a generally constant distance separates the fibers to promote uniform interaction of the blood and the fibers, which provides for better mixing of the blood and increased gas transfer rates. The hollow fibers 12 are also preferably maintained in a spaced relationship to maximize the surface area of the fibers that is in contact with the blood and to more uniformly distribute the blood flow over the fibers.

[042] The hollow fibers or gas-permeable tubes 12, which allow gas to be transferred to and from the blood of the patient, preferably have an inside diameter of about 120 micron and a length of about 15 to about 20 cm. The length and diameter of the fibers 12, however, may be larger or smaller depending, for example, upon the intended use of the intravascular blood-gas exchanger 10 and number of segments 14. Because the amount of gas transfer required will depend upon the size and condition of the patient, the number of hollow fibers 12 may be varied. For example, an intravascular blood-gas exchanger 10 for use with an infant may only have about one hundred hollow fibers while an adult may require 1500 or more hollow fibers to provide

adequate blood-gas exchange. Similarly, the size and length of the fibers could be varied accordingly to the amount of gas to be transferred.

[043] The hollow fibers 12 are gas-permeable structures that allow gas to be transported through the fibers and gas to be transferred to and from the blood. The hollow fibers 12 are constructed from a biocompatible material such as polypropylene coated with a siloxane, fluorinated polyurethane, or other state-of-the-art polymer. One skilled in the art will recognize that other suitable biocompatible materials could be used to construct the fibers 12, such as polyurethane, polyvinyl chloride, silicone and the like. Additionally, the hollow fibers 12 preferably have a microporous structure to facilitate the diffusion of gas through the walls of the fibers. The hollow fibers 26 may also include a thin, gas permeable coating, such as a siloxane, fluorinated polymer, or the like, with a thickness of approximately 0.1 micron to enhance the transfer of gas with the blood. One skilled in the art will appreciate that other suitable types of coatings may also be used depending upon the particular use of the intravascular blood-gas exchanger 10. Additionally, because the hollow fibers 12 are in contact with flowing blood, it is desirable to minimize thrombosis formulation. Accordingly, the hollow fibers 12 are preferably constructed from a thrombo-resistant material such as siloxane and preferably have a non-leachable, permanent covalently-bonded thromboresistant and blood compatible coating.

[044] The individual hollow fibers 12, as discussed above, are joined together to form one or more segments 14, and the intravascular blood-gas exchanger 10 can include any suitable number of segments such as six or eight. Advantageously, the fewer number of segments 14 generally decreases

the resistance to gas flow because the gas has a shorter distance to travel. On the other hand, multiple segments 14 provide additional opportunities for gas to be transported to and from the blood. Thus, one skilled in the art will appreciate that the number of segments 14 can vary upon the intended use of the intravascular blood-gas exchanger 10.

[045] The central gas conduit 16, which provides oxygen to the hollow fibers 12 and removes carbon dioxide from the device, has a double lumen configuration with an inner lumen 30 disposed inside an outer lumen 32. It will be appreciated that the lumens 30, 32 could also be positioned adjacent to each other or spaced apart. As best seen in Figure 3, the outer lumen 32 terminates near the distal end 20 of the blood-gas exchanger 10 and the inner lumen 30 terminates near the proximal end 18 of the blood-gas exchanger. The outer lumen 32 preferably transfers oxygen into the hollow fibers 12 and the inner lumen 30 preferably exhausts carbon dioxide from the hollow fibers. The central gas conduit 16 is preferably constructed from a flexible material such as plastic to allow the intravascular blood-gas exchanger 10 to be correctly positioned within the patient. The central gas conduit 16 also preferably has sufficient rigidity to support the hollow fiber segments 14 in the desired location. Thus, the central gas conduit 16 preferably has sufficient flexibility for insertion and removal of the intravascular blood-gas exchanger 10, and sufficient rigidity to maintain the device in the desired location.

[046] In greater detail, as best seen in Figure 3, the proximal end 18 of the blood-gas exchanger 10 includes a first mounting collar 34 and distal end 20 of the blood-gas exchanger 10 includes a second mounting collar 36 which enclose the ends of the hollow fibers 12 and permit gaseous communication

with the central gas conduit 16. In particular, the first mounting collar 34 encloses the proximal ends 22 of the hollow fibers 12 of the first segment 14 (e.g., the segment located at the proximal end 18 of the blood-gas exchanger) and allows gaseous communication between the hollow fibers and the inner lumen 30. The second mounting collar 36 encloses the distal ends 24 of the hollow fibers 12 of the last segment 14 (e.g., the segment located at the distal end 20 of the blood-gas exchanger) and allows gaseous communication between the hollow fibers and the outer lumen 32. The mounting collars 34 and 36 form an airtight enclosure around the ends of the hollow fibers 12 and the lumens 30, 32, respectively, to prevent the escape of gas into the blood stream of the patient, which could cause foaming and/or a potentially fatal air embolism. Preferably, the ends of the hollow fibers 12 are bound by a potting agent that forms at least a portion of the airtight enclosure around the ends of the hollow fibers and the lumens. The potting agent is preferably constructed from polyurethane, but other suitable types of materials such as epoxies, silicones, resins, etc. can also be used.

[047] As shown in Figure 1, the segments 14 are in the retracted position 26, which allows for easy insertion and removal of the intravascular blood-gas exchanger 10 from the patient. In this retracted position 26, the segments 14 preferably have an outside diameter of less than 12 mm. More preferably, they have an outside diameter of 7 mm or less. In contrast, conventional intravascular lung assist devices have an outside diameter of at least 12 mm or more. Thus, conventional lung assist devices require much more invasive surgery and a larger opening to insert and remove the device. Although not shown in the accompany figures, the segments 14 may be encased within a

compressible sleeve or vacuum compressed, for example, to form or maintain the segments in the retracted position.

[048] As shown in Figure 2, the segments 14 preferably have a generally conical shaped configuration that extends radially outward from the central gas conduit 16 in the expanded position 28. The generally conical-shaped hollow fiber segments 14 are preferably configured such that, in the expanded position 28, the radially outward extending portion of the segments touches or is located near the sidewall of the venae cavae or other suitable blood vessel. Advantageously, the generally conical-shaped hollow fiber segments 14 can be sized and configured to fit within different sized blood vessels, such as for a youth or adult patient. Additionally, the generally conical-shaped segments 14 can also be fully or partially expanded depending, for example, upon the size of the blood vessel. Thus, if the intravascular blood-gas exchanger 10 is inserted into a venae cavae with a smaller inside diameter than the outer diameter of the generally conical-shaped segments 14 in the expanded position 28, the segments can be only partially expanded and a new, smaller size intravascular blood-gas exchanger does not have to be inserted into the patient. Thus, the generally conical-shaped segments 14 allow the intravascular blood-gas exchanger 10 to be used in locations of various sizes and configurations.

[049] Preferably, the generally conical-shaped hollow fiber segments 14 extend radially outwardly from the central gas conduit 16 at an angle of at least 30° and, more preferably, at an angle of at least 45°. Desirably, the generally conical-shaped hollow fiber segments extend from the central gas conduit an angle of up to 90° such that the blood flow impacts the fibers at a relatively sharp or acute angle. Significantly, the impact of the blood flow at

an acute angle provides more direct contact of the blood with the fibers, which increases the gas transfer rates. Additionally, this acute angle of impact results in better mixing of the blood and helps eliminate stagnation areas where the blood and fibers do not interact. This acute angle of impact also helps prevent a boundary layer from developing, which limits the transfer of gas. Further, the acute angle of impact of the blood flow with the fibers creates more secondary blood flow, which also increases the gas transfer rate.

[050] Advantageously, by positioning the generally conical-shaped hollow fiber segments 14 at up to a right angle with respect to the blood flow, that increases the rate of gas transfer and provides better mixing of the blood during the interaction of the blood with the fibers 12. Significantly, by decreasing or eliminating stagnation areas and boundary layers, that effectively provides increased surface area for gas transfer.

[051] As best seen in Figure 3, the segments 14 are connected together in a series such that the hollow fibers 12 are continuous and extend from the proximal end 18 to the distal end 20 of the device. Fittings or couplings 38 are used to periodically hold the hollow fibers 12 proximate to the central gas conduit 16 and form the segments 14. In particular, the fittings 38 are located between the proximal ends 22 and distal ends 24 of hollow fibers 12 of the adjacent segments 14 and the fittings position the fibers proximate the central gas conduit 16. Thus, the fittings 38 hold the hollow fibers 12 in the desired position relative to the central gas conduit 16 and allow gas to flow from the fibers in one segment to the fibers in the adjacent segment. The fittings 38 are preferably slidably and non-rotatably attached to the central gas conduit 16, but the fittings may also be held in a fixed position or rotatable with respect to

the central gas conduit. Although not shown in the accompanying figures, the fittings 38 may also allow gaseous communication between the hollow fibers 12 and the central gas conduit 16. Additionally, the fittings 38 may be used to interconnect segments 14 formed by individual fibers 12 to allow gaseous communication between adjacent segments and/or the central gas conduit 16.

[052] As discussed above, in the preferred embodiment shown in Figures 1-3, the segments 14 have a generally conical-shaped configuration in which the fibers 12 are folded or compressed about the central gas conduit 16 in the retracted position 26 and the segments extend radially outward in the expanded position 28. The first segment 14 near the proximal end 18 of the blood-gas exchanger 10 will be described in detail, and the other segments preferably have a similar configuration. The segment 14 includes a first portion 40 with a first end 42 that is connected to the first mounting collar 34 and a second end 44 that is connected to a curved second portion 46. The second portion 46 is also connected to the first end 48 of a third portion 50 and the third portion includes a second end 52 that is held in position by the fitting 38. That is, the first portion 40 extends from the first mounting collar 34 to the second portion 42, which is a curved section that interconnects the first and third portions. The third portion 44 extends from the second portion and is held in position by the fitting 38. The first and third portions 40, 50 are preferably generally straight in order to minimize the length of the fibers 12, which advantageously decreases gas flow resistance. The second portion 42 is disposed outwardly from the central gas conduit 16 in the expanded position 28 and preferably connected to the first and third portions at an angle greater than 90°. More preferably, the second portion 42 is angled at an angle

approaching 180° to minimize the length of the fibers 12. Thus, for each generally conical-shaped segment 14, blood flows past both the first portion 40 and the third portion 50. Therefore, the blood passes by at least two sections of hollow fibers 12 for each generally conical-shaped segment 14.

[053] In the preferred embodiment shown in Figures 1-3, the generally conical-shaped hollow fiber segments 14 extend outwardly from the central gas conduit 16 at an angle relative to the central gas conduit 16. Preferably, the first portion 40 of the segments 14 are located at an angle of at least 30° with respect to the central gas conduit 16, and more preferably at an angle of 45° or more. Advantageously, the greater the angle of the fibers 12 relative to the central gas conduit 16, the shorter the length of the fibers. Significantly, the shorter length fibers 12 allow greater gas flow rates because of decreased resistance to gas flow within the fibers. Additionally, the larger angle provides greater mixing of the blood without significantly increasing resistance to the blood flow because the blood flow is at an acute angle with respect to the fibers. Further, this arrangement or pattern of the fibers provides more effective surface area for gas transfer, which allows more oxygen to be provided to the blood and more carbon dioxide to be removed. Laboratory testing by applicants indicated that this configuration of the generally conical-shaped fiber segments 14 allows approximately 224 ml of oxygen per minute to be transferred into circulating venous blood. This laboratory testing also indicated that approximately 145 ml of carbon dioxide per minute may be transferred from circulating venous blood, which is approximately two to four times more than can be achieved by conventional lung assist devices. Of course, these figures were merely the result of

laboratory testing of one embodiment of the present invention. It should be recognized that a wide range of oxygen and carbon dioxide transfer rates are possible using this and other embodiments of the present invention, including transfer rates significantly lower or higher than that achieved in laboratory testing of this one embodiment.

[054] Disposed proximate the second portion 46 of the fibers 12 is a generally ring-shaped support structure 54. The generally ring-shaped support structure 54 is used to guide and/or control the expansion of the generally conical-shaped fiber segments 14. In particular, the support structure 54 includes a flexible or expandable member 56 that allows the hollow fibers 12 to expand a given distance away from the central gas conduit 16 in the expanded position 28. Preferably, the member 56 is constructed from spring steel and is located within the curved portion of the hollow fibers 46. The spring steel member 56 causes the conical-shaped fiber segments 14 to expand into the expanded position 28. One skilled in the art will appreciate that the support structure 54 can also be constructed from other suitable types of materials such as plastics, metals and the like. Further, the support structure 54 could cause the segments 14 to expand by other means such as filling the support structure with fluid or heating of the support structure such that it expands. It will be appreciated that the support structure 54 could also be designed such that the blood flow or removal of a protective sheath causes the conical-shaped fiber segments 14 to expand into the expanded position 28. It will also be appreciated that the support structure 54 may be rigidly attached or slidably attached to either the fibers 12 or the central gas conduit 16

depending, for example, upon the desired configuration of the support structure.

[055] The intravascular blood-gas exchanger 10 may also include one or more struts or support members 58 that are connected to the support structure 54. The struts 58 may also be connected to the collars 34, 36, fittings 38 or central gas conduit 16 to assist in opening the generally conical-shaped fiber segments 14 and/or maintaining the conical-shaped fiber segments in the expanded position 28. The struts 58 are preferably constructed from a generally rigid material such as steel or plastic and the struts have a generally straight or curved configuration. Preferably, the struts 58 have a slightly concave configuration and the struts are positioned to both assist in opening the generally conical-shaped fiber segments 14 and maintaining the segments in the open position 28. In particular, the struts 58 are preferably configured to work in conjunction with the support structure 54 to slidably expand and retract the segments 14 like an umbrella. One skilled in the art will appreciate there are other diverse ways to move the segments 14 between the retracted 28 and expanded positions 30, and the preferred embodiments disclosed herein should not be construed as limiting to the scope of the invention.

[056] In order to selectively adjust the overall outside diameter of the segments 14, the second mounting collar 36 and the fittings 38 are preferably moved towards the first mounting collar 34, which causes the segments to expand radially outward. Preferably the outer lumen 32 is moved towards the proximal end 18 of the blood-gas exchanger 10 while the inner lumen 30 is held in a relatively stationary position. This causes the segments 14 to expand radially outward and the fittings 38 to move towards the proximal end 18 of

the blood-gas exchanger 10. In order to retract the blood-gas exchanger 10, the outer lumen 32 is moved away from the proximal end 18 of the blood-gas exchanger 10 and this causes the segments 14 to retract into the retracted position 26. It will be appreciated that the inner and outer lumens 30, 32 could move in any suitable motions or relationships to cause the segments 14 to expand or retract. Additionally, one skilled in the art will understand that other components such as another lumen, a metal rod, twisting of the lumens, etc., could be used to expand and retract the segments.

[057] Figures 4 and 5 depict another preferred embodiment of the intravascular blood-gas exchanger 10 illustrating the arrangement of the segments 14 about the central gas conduit 16. As seen in Figure 4, the segments 14 are in the retracted position 26 with the fibers 12 disposed proximate the central gas conduit 16. As seen in Figures 5 and 6, the segments 14 radially extend outwardly from the central gas conduit 16 at an angle of about 75° to 90°. Advantageously, the acute angle between the blood flow and the hollow fibers 12 promotes increased gas transfer and better mixing of the blood. As best seen in Figure 6, the support structure 54 is preferably a ring-shaped member 60 that hold the fibers 12 in the desired locations relative to the central gas conduit 16. Thus, it will be appreciated that the segments 14 can extend radially outwardly from the central gas conduit 16 at a variety of angles, include up to 90° or more.

[058] In use of a preferred embodiment of the intravascular blood-gas exchanger 10, the segments 14 are positioned in the retracted position 26 by folding the fibers 12 about the central gas conduit 16. It will be appreciated that the fibers 12 or segments 14 can also be encased within a flexible,

compressible sleeve and/or compressed by vacuum pressure. As discussed above, the folding or furling of the fibers 12 into the retracted position 26 makes the intravascular blood-gas exchanger 10 smaller and easier to insert into the patient. Advantageously, the small outside diameter of the segments 14 in the retracted position 26 allow the device to be inserted into smaller diameter blood vessels, such as iliac or jugular veins. The blood-gas exchanger 10 can then be moved within the body into the desired location such as the venae cavae. One skilled in the art will recognize that, for safety reasons, it is important to hydrate the hollow fibers 12 and to remove any air bubbles which might remain between the fibers prior to inserting the device within the venae cavae.

[059] Once the intravascular blood-gas exchanger 10 is in place, the outer lumen 32 is connected to a source of oxygen-enriched gas and inner lumen 30 is connected to a vacuum or some other exhaust system. As a result, oxygen-enriched gas travels through the outer lumen 32, into the second mounting collar 36, and then into the distal end 20 of the hollow fibers 12. During the time the oxygen-enriched gas is within the hollow fibers 12 it will oxygenate the blood traveling through the venae cavae. In addition, carbon dioxide will pass from the blood into the fibers and thereby be removed from the blood stream. As discussed above, oxygen and carbon dioxide can readily travel through the walls of fibers 12, but blood cannot enter the tubes. Thus, oxygenation can occur without the blood being directly exposed to gas bubbles.

[060] It is preferred that the intravascular blood-gas exchanger 10 operates at subatmospheric pressures. In particular, oxygen-enriched gas (preferably

nearly 100% oxygen) is introduced into the outer lumen 32 at about atmospheric, or slightly above atmospheric, pressure. A vacuum (not shown) is attached to the inner lumen 30 to provide the necessary pressure difference to cause the oxygen gas to flow through the hollow fibers 12. The oxygen gas experiences a pressure drop as it flows through the outer lumen 32 towards the hollow fibers 12. As a result, the pressure of the oxygen gas as it enters the hollow fibers 12 is subatmospheric.

[061] Operation of the intravascular blood-gas exchanger 10 at low pressure will enhance carbon dioxide removal, while providing adequate blood oxygenation. The driving force behind blood gas transfer is the difference between the partial pressures of the oxygen and carbon dioxide in the blood stream and the partial pressures of the oxygen and carbon dioxide in the hollow fibers 12. Lowering the pressure within the fibers 12 necessarily promotes transfer of carbon dioxide from the blood into the fibers. Advantageously, because nearly pure oxygen is used in the intravascular blood-gas exchanger 10, the partial pressure of oxygen is sufficiently high to achieve adequate blood oxygenation.

[062] Traditionally, blood oxygenation has been the primary goal in patients suffering from acute respiratory failure. It has been found, however, that removal of carbon dioxide from blood is also important. Thus, operation of the intravascular blood-gas exchanger 10 at subatmospheric pressures enhances the overall effectiveness of the device. Moreover, because the operating pressure is preferably less than the blood pressure, any leak in the intravascular blood-gas exchanger 10 cannot introduce air bubbles within the blood stream. Any such leak would introduce blood within the hollow fibers

12, sealing the leak, rather than allow gas to enter the blood stream. Therefore, operation of the intravascular blood-gas exchanger 10 at subatmospheric pressures provides significant safety benefits.

[063] Although the above discussion has described oxygen being introduced through the outer lumen 32, it will be appreciated that the intravascular blood-gas exchanger 10 can also operate with oxygen being introduced through the inner lumen 30 and into the first mounting collar 34, with oxygen then flowing through the hollow fibers 12 and into the second mounting collar 36, and finally being removed through the outer lumen 32. Oxygen introduced through the inner lumen 30 is preferably at a subatmospheric pressure to compensate for the pressure drop across the outer lumen 32.

[064] While the disclosed invention is capable of reproduction in a wide variety of forms and specific embodiments, by way of example, some of the specifications of two preferred embodiments of the present invention will now be set forth. One of these embodiments consists of approximately 3,200 hollow fibers, each of which is approximately 13.6 cm long. The inner diameter of the hollow fibers of this embodiment is approximately 120 microns, while the outer diameter of the hollow fibers is approximately 167 microns. The gas transfer membrane surface area of this embodiment is approximately 2,600 cm2. The maximum diameter of the fiber bundle at potting is approximately 6.7 mm, and the maximum diameter of the bundle in the compacted or furled mode (for insertion into a blood vessel) is approximately 9.0 mm. When the device is expanded, this embodiment displaces approximately 28 ml of fluid. The fiber packing density is approximately 9.3%. The gas flow rate through the hollow fibers varies from

approximately 1.8 L/min at 100 torr suction to approximately 3.5 L/min suction at 400 torr. The pressure drop in the liquid phase varies from approximately 5 mm Hg at a flow rate of 1.0 L/min to approximately 12 mm Hg at a flow rate of 2.0 L/min to approximately 28 mm Hg at a flow rate of 4.0 L/min. This embodiment ultimately transfers approximately 88 ml of oxygen per minute into circulating venous blood and transfers approximately 62 ml of carbon dioxide per minute out of circulating venous blood.

[065] A second preferred embodiment of the blood-gas exchanger has the following specifications. This embodiment has approximately 4,800 hollow fibers, each of which is approximately 17.5 cm long. The inner diameter of the hollow fibers of this embodiment is approximately 120 and 190 microns, while the outer diameter of the hollow fibers is approximately 167 and 250 microns. The gas transfer membrane surface area of this embodiment is approximately 4,517 cm2. The maximum diameter of the fiber bundle at potting is approximately 6.7 mm, and the maximum diameter of the bundle in the compacted or furled mode (for insertion into a blood vessel) is approximately 7.3 mm. When the device is expanded, this embodiment displaces approximately 55 ml of fluid. The fiber packing density is approximately 18.3%. The gas flow rate through the hollow fibers varies from approximately 2.8 L/min at 100 torr suction to approximately 4.5 L/min suction at 400 torr. The pressure drop in the liquid phase varies from approximately 20 mm Hg at a flow rate of 1.0 L/min to approximately 45 mm Hg at a flow rate of 2.0 L/min to approximately 90 mm Hg at a flow rate of 4.0 L/min. This embodiment ultimately transfers approximately 224 ml of

oxygen per minute into circulating venous blood and transfers approximately 145 ml of carbon dioxide per minute out of circulating venous blood.

[066] Although the invention has been described in connection with certain preferred embodiments, other embodiments apparent to those of ordinary skill in the art are also within the scope of the invention. Accordingly, the described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is intended to be defined only by the appended claims. It will also be understood that the principles of the present invention can be applied to other types of medical devices and not only intravascular blood-gas exchangers.

[067] What is claimed is:

CLAIMS

1. A blood-gas exchanger that enables a transfer of oxygen and carbon dioxide into and out of circulating venous blood, the blood-gas exchanger comprising:

a plurality of hollow fibers capable of carrying oxygen and carbon dioxide, the plurality of hollow fibers capable of moving between a first position and a second position;

a central gas conduit at least partially disposed within the plurality of hollow fibers, the central gas conduit allowing oxygen to be provided to the plurality of hollow fibers and allowing carbon dioxide to be exhausted from the plurality of hollow fibers;

the plurality of hollow fibers being located proximate the central gas conduit in the first position; and

the plurality of hollow fibers extending radially outward in a generally conical-shaped configuration from the central gas conduit in the second position.

a means for connecting at least a first end of the microporous hollow fibers to the central gas conduit by mounting collars having:

2. The blood-gas exchanger of Claim 1, further comprising a support structure that is used to control the movement of the plurality of hollow fibers between the first position and the second position.

3. The blood-gas exchanger of Claim 1, further comprising a support structure that is used to maintain the plurality of hollow fibers in the generally conical-shaped configuration in the second position.

4. The blood-gas exchanger of Claim 1, further comprising one or more struts that are used to control the movement of the plurality of hollow fibers between the first position and the second position.

5. The blood-gas exchanger of Claim 1, further comprising one or more struts that are used to maintain the plurality of hollow fibers in the generally conical-shaped configuration in the second position.

6. The blood-gas exchanger of Claim 1, wherein the plurality of hollow fibers open like an umbrella when moving from the first position to the second position; and wherein the plurality of fibers close like an umbrella when moving from the second position to the first position.

7. The blood-gas exchanger of Claim 1, wherein the plurality of hollow fibers extend radially outwardly in the second position at an angle of about 30° relative to the central gas conduit.

8. The blood-gas exchanger of Claim 1, wherein the plurality of hollow fibers extend radially outwardly in the second position at an angle of about 60° relative to the central gas conduit.

9. The blood-gas exchanger of Claim 1, wherein the plurality of hollow fibers extend radially outwardly in the second position at an angle of about 90° relative to the central gas conduit.

10. The blood-gas exchanger of Claim 1, further comprising a plurality of fittings that divide the plurality of hollow fibers into segments, the segments extending radially outward from the central gas conduit in the second position.

11. The blood-gas exchanger of Claim 10, wherein the segments include a generally straight first portion, a curved second portion and a generally straight third portion.

12. The blood-gas exchanger of Claim 1, further comprising mounting collars that fluidly connect the plurality of hollow fibers to the central gas conduit.

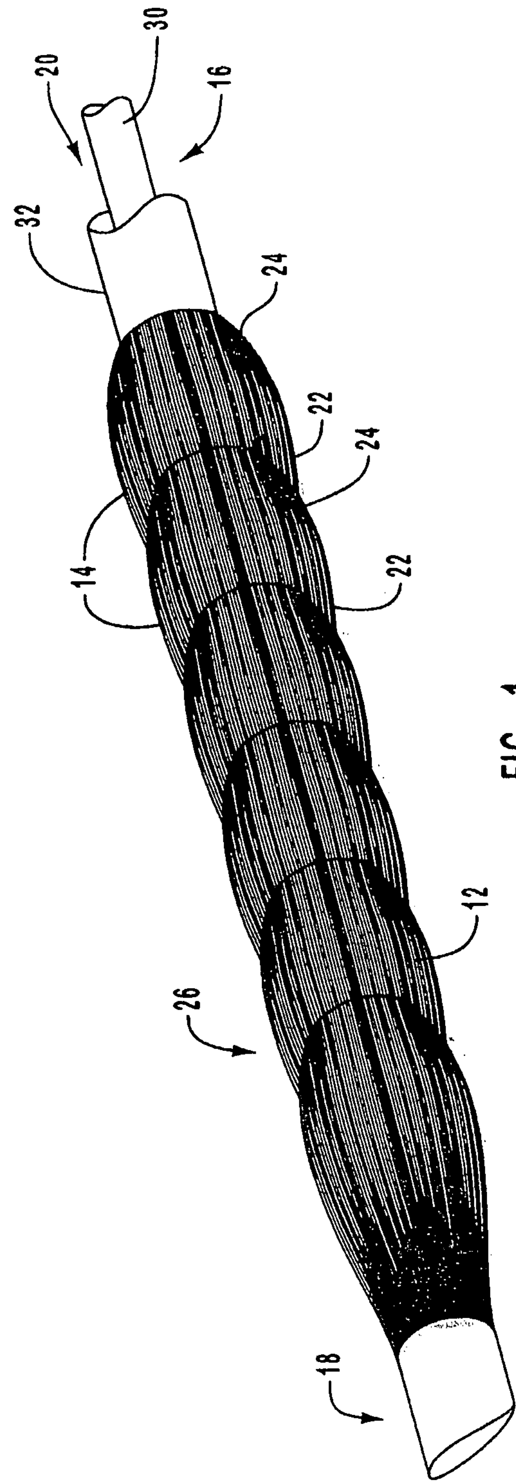

FIG. 1

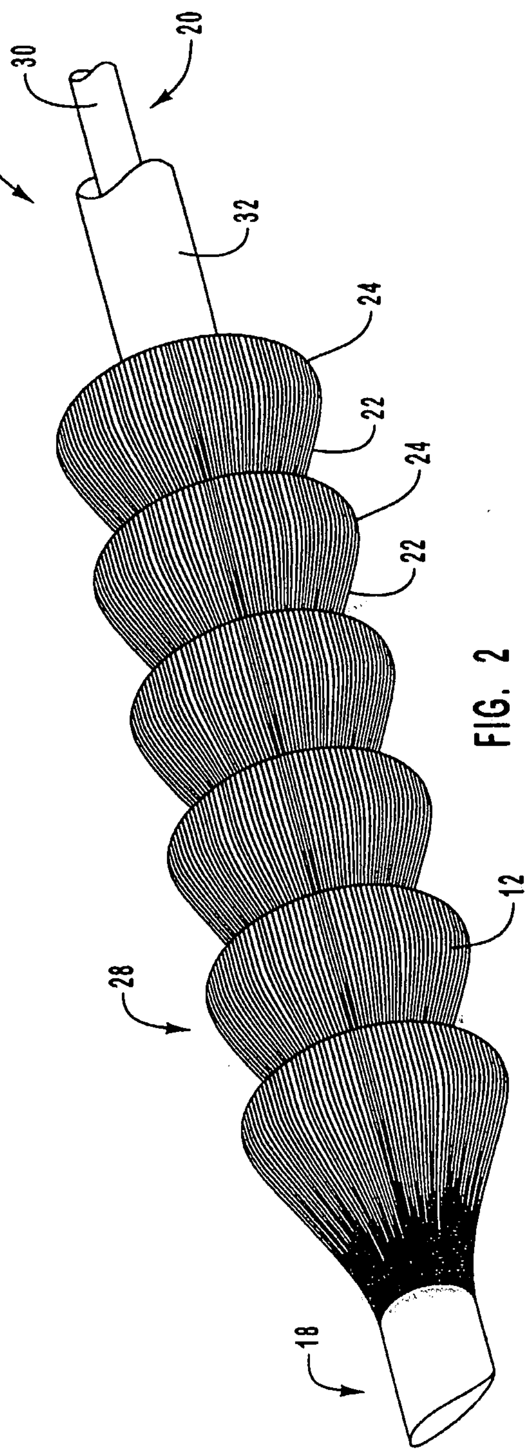

FIG. 2

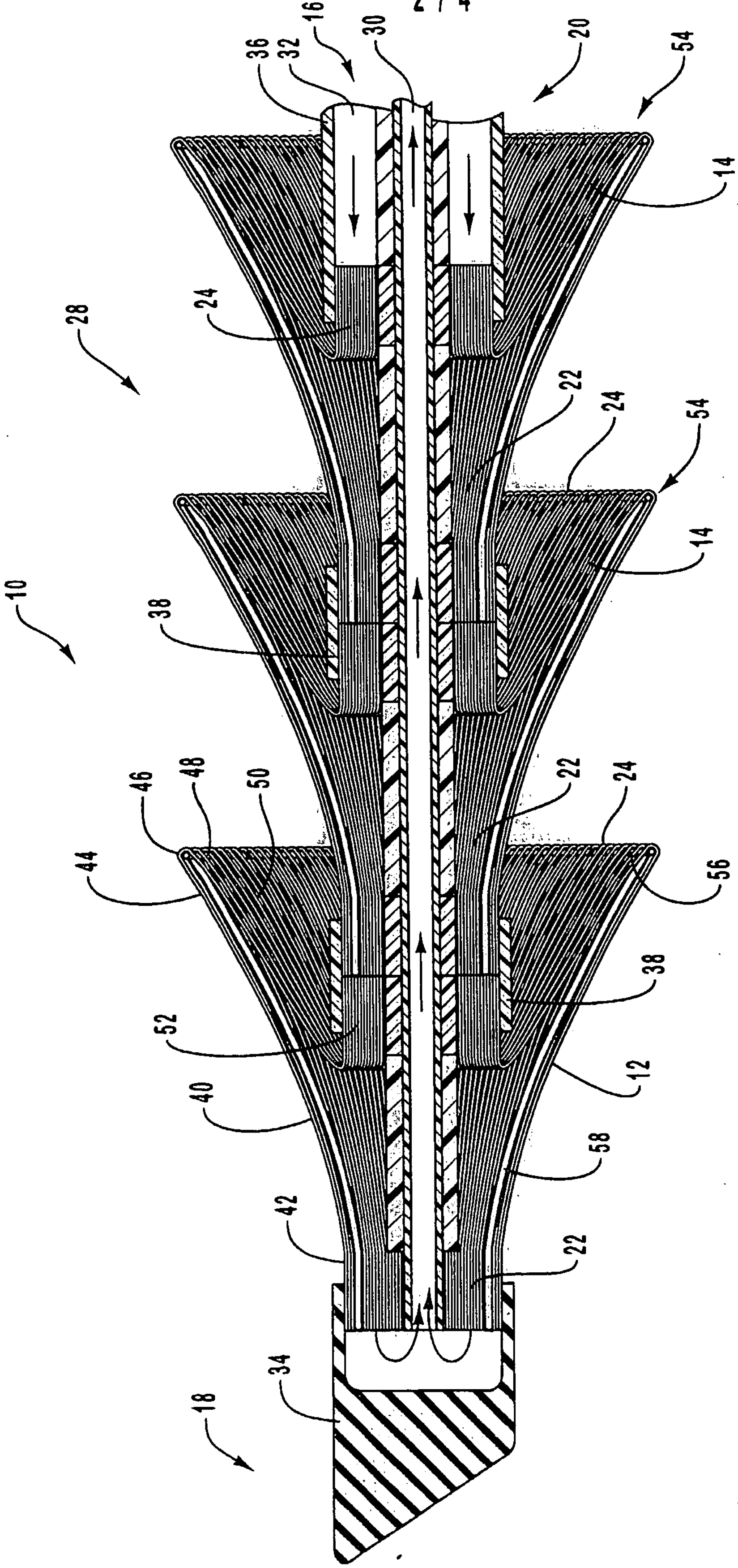
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FIG. 3

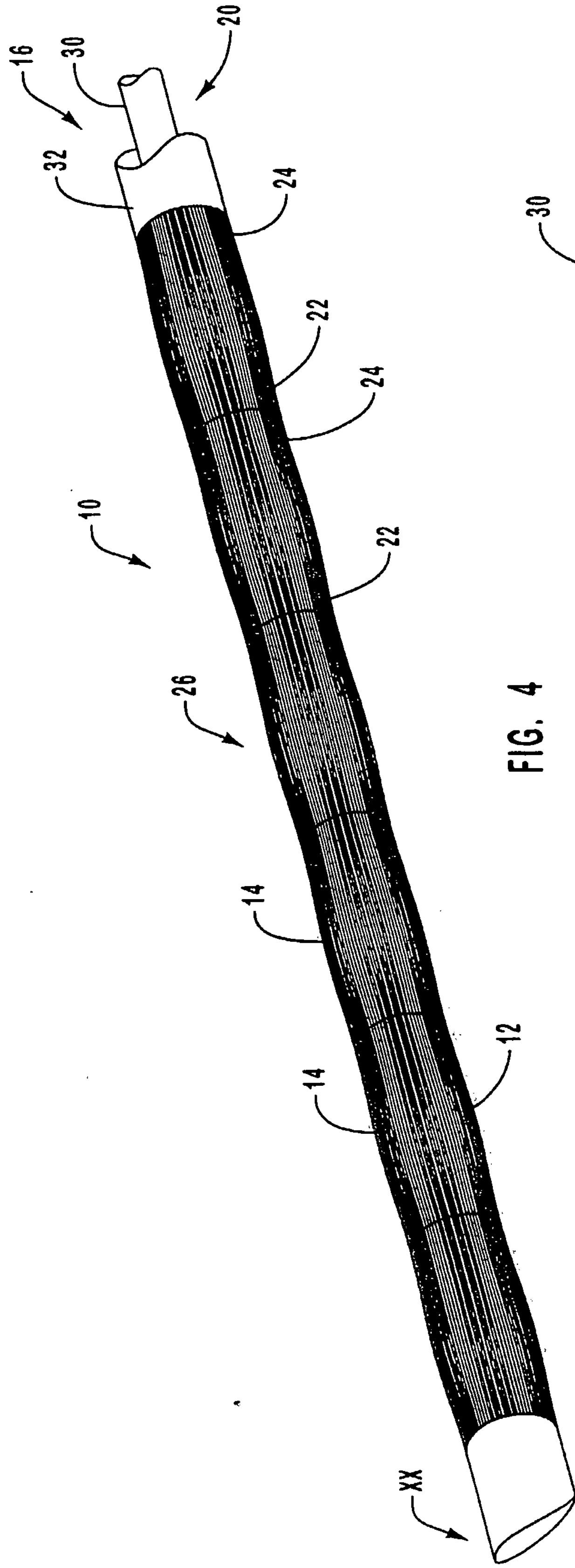

FIG. 4

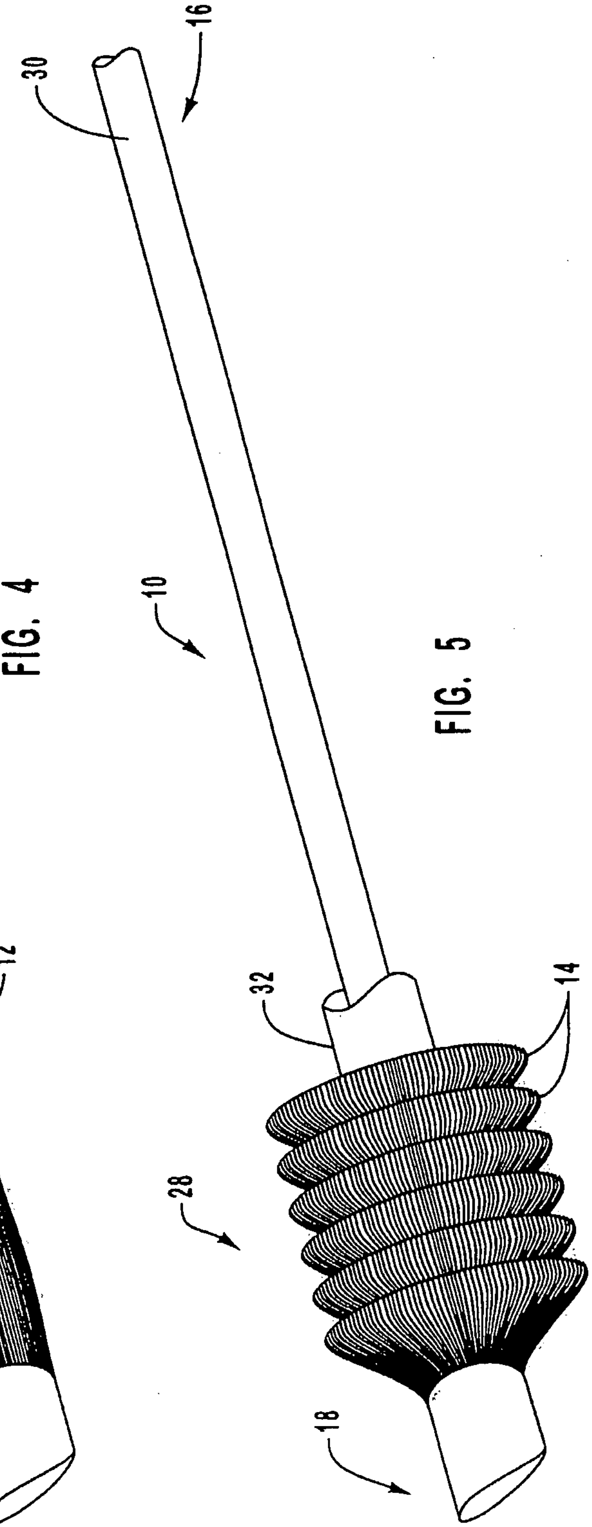

FIG. 5

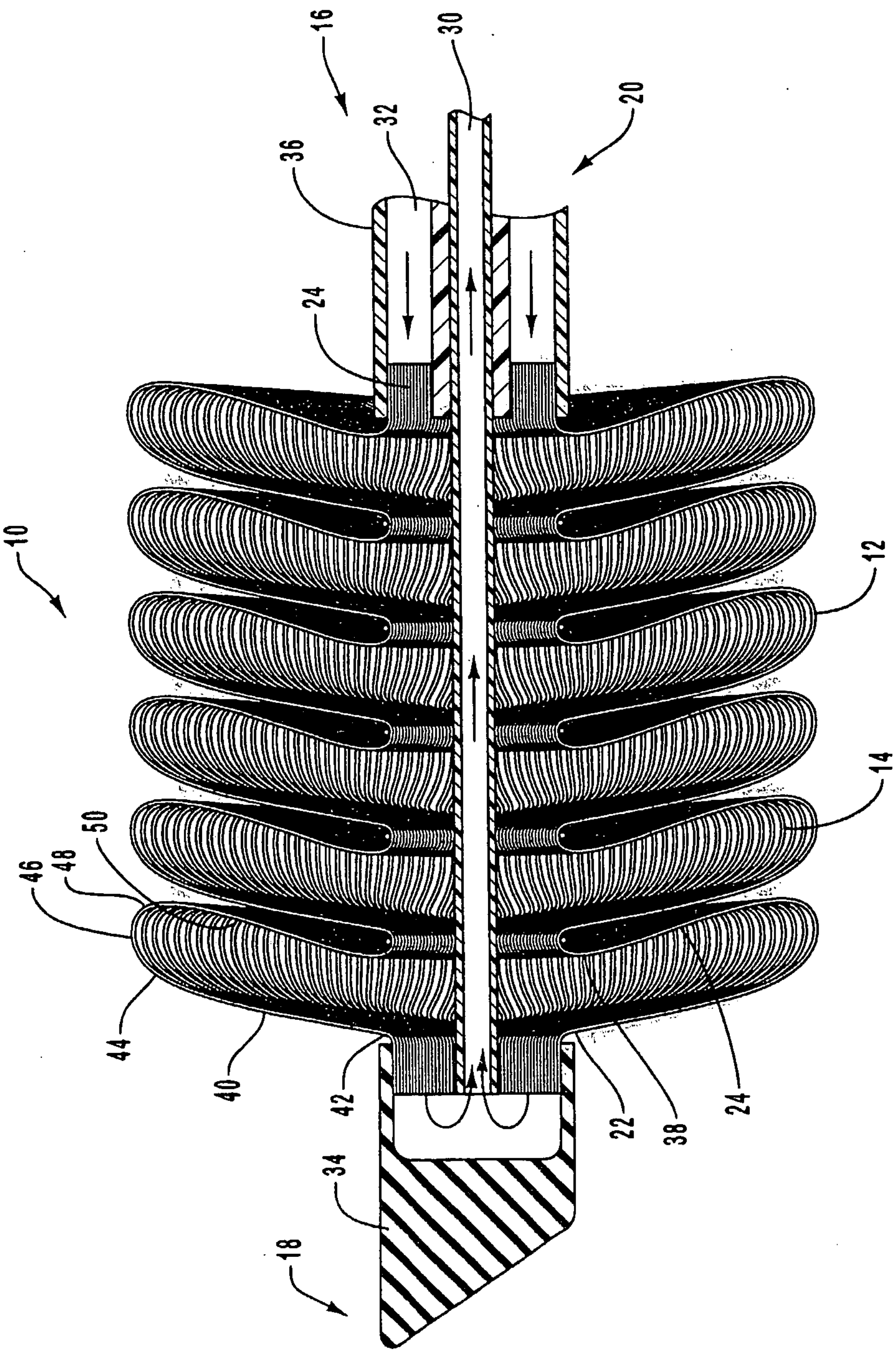

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/08078

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 037 383 A (VASLEF STEVEN N ET AL) 6 August 1991 (1991-08-06) column 3, line 42 - line 66 column 4, line 46 -column 5, line 32 column 6, line 4 - line 26; figures 4,5,8 ---	1,2,7-12 3-6
X	US 5 487 727 A (SNIDER MICHAEL T ET AL) 30 January 1996 (1996-01-30) column 4, line 58 - line 65 column 7, line 11 - line 35; figures 6,8,9E ---	1,2, 6-10,12
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 July 2002	24/07/2002

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/08078

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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